

**Amendment and Response**

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Serial No.: 09/762,224

Confirmation No.: 2859

Filed: 30 July 2001

For: PSEUDOTYPED RETROVIRUSES AND STABLE CELL LINES FOR THEIR PRODUCTION**Remarks**

Reconsideration and withdrawal of the rejections of the claims, in view of the remarks presented herein, is respectfully requested. Claims 1-55 are pending. Of these, claims 1-12, 19-29, 33-38, 40-43 and 53 are under examination. Claims 1-3, 19, 25, 27, 28, 34, 40 and 53 are amended. Support for the amendments to claims 1, 19 and 53 is found throughout the specification at, for example, page 11, line 12 to page 12, line 2 and page 17, line 16 to page 18, line 2. Support for the amendments to claims 2, 3, 25, 27, 28, 34 and 40 is found in the specification at page 21, line 24. Claims 13-18, 30-32, 39, 44-52, 54 and 55 are withdrawn from consideration with reservation for later presentation.

**The 35 U.S.C. §112, Second Paragraph, Rejection**

The Examiner rejected claims 1-12, 19-29, 33-38, 40-43 and 53 under 35 U.S.C. § 112, second paragraph, alleging that the claims are indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. These rejections are respectfully traversed.

A patent claim is sufficiently definite to satisfy 35 U.S.C. § 112, second paragraph if one skilled in the art would understand the bounds of the claim when read in light of the specification. Exxon Research v. United States, 60 USPQ2d 1272, 1277 (Fed. Cir. 2001) (citing Miles Labs., Inc. v. Shandon, Inc., 27 USPQ2d 1123, 1126 (Fed. Cir. 1993)).

Concerning claims 1-12, 19-29 and 53, the Examiner alleges that the claims are vague and indefinite for failing to clearly set forth how the four nucleotide sequences referred to in the claims are structurally related to each other.

Applicants have amended claims 1, 19 and 53 to clarify that each of the four nucleotides referred to in the claims operably encodes a retroviral Gag, Pro, Pol or viral glycoprotein. As such, designation of a specific structural relationship of the four nucleotide sequences referred to in the claims to each other is not necessary because workers of skill in the art realize that the nucleotide sequences can function independently, or in any combination, relative to each other. The independent nature of the nucleotide sequences is indicated by the Applicants within the

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specification where arrangement of the nucleotide sequences in a plethora of ways is described (for example; page 11, lines 12-18 and page 16, line 29 to page 17, line 30).

Applicants emphasize that expression of the four nucleotide sequences within a cell provides for assembly of a pseudotyped retrovirus because the polypeptides can assemble to form a pseudotyped retrovirus regardless of whether or not they were expressed independently of each other or in a linked manner within a cell. Therefore, there is no requirement that the specific structural relationship (e.g., one or multiple vectors, tandem or non-tandem arrangement) of the four nucleotides be specifically defined. Accordingly, it is respectfully submitted that those of skill in the art can readily determine the scope of the claims without the necessity of defining the specific structural relationship of the four nucleotides to each other because the sequences do not require such a definition.

The Examiner asserts that claims 33-38 and 40-43 are vague and indefinite for failing to clearly set forth the salient characteristics of a pseudotyped retroviral particle. The Examiner also alleges that the properties of a protein or nucleic acid that is a "desired protein" or a "desired ribonucleotide sequence" are not readily manifest.

With regard to claim 33, the claim is directed to a pseudotyped retrovirus having at least two different viral glycoproteins disposed in the lipid bilayer that surrounds the retroviral capsid.

With regard to claim 40, the claim is directed to use of a pseudotyped retrovirus having at least two different viral glycoproteins disposed in the lipid bilayer that surrounds the retroviral capsid to transduce a desired ribonucleotide sequence into a cell.

The specification clearly states that the present disclosure is the first report of a pseudotyped retrovirus having at least two different viral glycoproteins disposed in its lipid bilayer (page 8, lines 25-28). Applicants submit that those of skill in the art would readily understand a salient characteristic of the claimed pseudotyped retrovirus to be the presence of at least two different viral glycoproteins disposed in the lipid bilayer that surrounds the retroviral capsid.

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Applicants have provided those of skill in the art guidance as to the identity of a "desired protein" or a "desired ribonucleotide sequence" throughout the specification.

"In a further preferred form of the present invention, the eukaryotic cells described above may include another nucleotide sequence that encodes a desired protein so that they may produce pseudotyped retroviruses having an RNA genome including such desired nucleotide sequences. The protein can be such that it provides a beneficial or therapeutic effect if introduced into an animal. For example, a gene may encode a protein that is needed by an animal, either because the protein is no longer produced, is produced in insufficient quantities to be effective in performing its function, or is mutated such that it either no longer functions or is only partially active for its intended function." (page 15, lines 17-26)

A "desired protein" is any protein of interest to an artworker practicing the claimed invention. In order to clarify the invention, the claims have been amended to recite a "selected" protein or a "selected" ribonucleotide sequence in place of a "desired" protein or ribonucleotide sequence. It is respectfully submitted that this amendment is a clarifying amendment only and does not narrow the scope of the claims.

Applicants respectfully submit that the requirements of 35 U.S.C. § 112, second paragraph are satisfied because one of skill could determine the scope of the claims based on the guidance provided by the specification and what was known in the art. Accordingly, the Examiner is respectfully requested to withdraw the rejections of the claims under 35 U.S.C. § 112. Applicants respectfully request an additional non-final Office Action to clarify what the Examiner regards as "salient characteristics" in the event that a Notice of Allowance is not issued following submission of this Response.

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It is respectfully submitted that the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for  
Purdue Research Foundation

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**CERTIFICATE UNDER 37 CFR §1.8:**

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 19<sup>th</sup> day of May, 2004, at 11:35am (Central Time).

By:

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